Office Action Summary	Application No.	Applicant(s)	
	10/676,568	KLAUTKY ET AL.	
	Examiner	Art Unit	
	Lyle A. Alexander	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 1998*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-15,21-26 and 28-38* is/are pending in the application.

4a) Of the above claim(s) *30-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-15,21-26,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *2/5/09* .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

This Office action is in response to the 2/5/09 Interview Summary where Applicants' correctly noted several typographical error regarding the rejection of canceled claims. This Office action will correct the typographical error and not change any of the substantive issues from the previous 1/13/09 Office action.

The Office notes that new claims 30-31 and 33-39 have been renumbered under Rule 126 as claims30-38 respectively.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 4-15, 21-26, 28-29, drawn to a method of determining if a specimen is adequate for cytological slide preparation, classified in class 436, subclass 177.

II. Claims 30-33, drawn to a method of determining cell concentration, classified in class 436, subclass 63.

III. Claims 34-38, drawn to a method of performing an assay to detect human papilloma virus, classified in class 435.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II,III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination II has separate utility such as a method for determination of cellular volume and

subcombination III has separate utility to detect human papilloma virus. See MPEP § 806.05(d).

Inventions II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination III has separate utility such as detection of human papilloma virus. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Newly submitted claims 30-38 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: See the above restriction requirement.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 30-39 are withdrawn from consideration

as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-15, 21-26 and 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite what parameters are intended that designate a sample as satisfactory for preparing a specimen slide. Additionally, claim 1 is not clear what method is performed by the "manipulation designator designates" and what/how the required manipulation determined. For the purposes of examination, the claimed "positive designator" will be interpreted as making a first optical measurement and making a determination about the sample based upon the first measurement . The claimed "manipulation designator" will be interpreted as performing the appropriate step so proper analysis can be achieved.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,6,9-11,15, 22, 24, 26 and 28-29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Zahniser et al. (USP 5,168,066).

Zahniser et al. teach an automated method of cellular analysis. The cells are treated with a thionin stain that contrasts the cellular nuclear portion from the cytoplasm. Column 6 lines 13-16 teach fixing the cells on the slide with an alcoholic fixing solution. This has been read on the claimed “providing a cytological sample in a solution in a vessel.” The stained cell is subjected to IR and electronically imaged. The subsequent image is stored and compared to predetermined parameters to diagnosis the health of the cells. The claimed "optical interrogating" has been read on the taught electronic imaging. The claimed "attaching a positive designator to the sample ....attaching a manipulation designator" have been read on the taught steps of recording the image and comparison to certain parameters to obtain a diagnosis. Column 2 lines 24-35 teach use of stain that includes the claimed "acetic acid" and the claimed “reducing agent” (e.g. sodium or potassium hydroxide).placement of a tissue sample on a slide.

The 10/13/08 amendments have added the limitations that the positive designator identifies if the sample is satisfactory for slide preparation and the manipulation designator identifies what further steps must be performed for an unsatisfactory sample to become satisfactory. Zahniser et al. teach in paragraph[26-28] illuminating the sample to determine which specific stain was used. This has been read on the claimed "positive designator” because based upon this analysis the determination of which analysis, if any, would be satisfactory for analysis. The determination of the proper wavelength for analysis has been read on the “manipulation designator” because this step determines conditions (e.g. wavelength) to render proper analysis.

Claims 1,4-15, 21-26 and 28-29 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Isenstein et al. (US 2004/0253144).

Isenstein et al. has an earlier effective filing date and a different inventive entity which makes it available as prior art. Figures 5-12 teach various decision trees that encompass the claimed automated method of classifying and analyzing the samples.

More specifically, figure 6 describes procuring a sample(110), generating a slide preparation(114) from the sample, reviewing/marking/counting the cells(116) and determination if the slide is properly prepared(118). These steps have been read on the claimed "positive designator designates the sample as satisfactory for preparing a specimen." because based upon this analysis the determination(118) is made of which analysis, if any, would be satisfactory for analysis. Step(122) determines if the sample requires further manipulation and processes the sample appropriately. These steps have been read on the "manipulation designator designated the sample as requiring a manipulation ".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4-5,7-8 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zahniser et al. in view of Zweig et al. (USP 6,629,057).

See Zahniser et al. Supra.

Zahniser et al. are silent to the claimed designator relating to the volume of sample.

Zweig et al. teach a method for verifying accurate test performance of automated analysis testing systems by routine quality control testing. Column 5 lines 7-34 teach it is desirable to detect user errors such as sufficient sample volume and abnormal reaction chemistry. The Office has read the determination of sufficient on the claimed steps of ".... meets the criterion if it contains sufficient cells for performing the assay" of claim 4, the "... sample is satisfactory for automated slide preparation" of claim 6, “adequate quantity” of claim 7, “additional sample is needed for performing the assay” of claim 8 and “concentration of the cells in the sample” of claims 12-13. The Office has read the claimed “treatment of sample” of claim 9, the addition of “acetic acid” of claim 10, the addition of “reducing agent” on claim 11 on the taught steps of determining abnormal reaction chemistry (e.g. the Office notes Zahniser et al. teach both acetic acid and a reducing agent in column 2 lines 24-35 as part of the reaction chemistry).

It would have been desirable to modify Zahniser et al. in view of Zweig and employ the above quality control measures to gain the advantages of having greater certainty of the validity of the results.

Claims 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zahniser et al.

See Zahniser et al. Supra.

Zahniser et al. are silent to placing a "marking on the vessel" to indicate information or the status of the sample.

The basic technique of putting indicia on data which then enabled standard sorting, searching, and reporting yielded no more than the predictable outcome which one of ordinary skill would have expected to achieve with this common tool of the trade and was therefore an obvious expedient. The Court held that "[t]he gap between the prior art and respondent's system is simply not so great as to render the system nonobvious to one reasonably skilled in the art."Id. at 230, 189 USPQ at 261.

It would have been within the skill of the art to modify either Zahniser et al. and place indicia on the sample container to enable sorting and searching as an obvious expedient.

Response to Arguments

Applicant's arguments filed 10/13/08 have been fully considered but they are not persuasive.

The 10/13/08 amendments have obviated the provisional rejections on the ground of nonstatutory obviousness-type double patenting and the art rejections over Bukshpan et al.

Applicants traversed the rejection over Zahniser et al. on the basis this reference fails to teach the claimed "positive designator" and "manipulation designator." The Office maintains this language is sufficiently broad to have been read on the taught steps of recording the image and comparison to certain parameters to obtain a diagnosis. Specifically, Zahniser et al. compares the image to a standard or known image and designates the sample image is either normal or abnormal which has been properly read on the claimed positive designator and manipulation designator. The analysis of the image and designation as either normal or abnormal cells has been read on attaching a designator.

Applicants state Isenstein et al. fails to teach any of the claimed method steps. The Office has particularly pointed out above how figure 6 of Isenstein et al. reads on the instant claims. The Office maintains the rejections over Isenstein et al. are proper.

Applicants state Isenstein et al. teach a method for screening and identifying biological sample and cannot be read on the instant claims that are directed to the claimed method of classifying cytological samples. The Office maintains the instant claim language is sufficiently broad to have been properly read on the instant claims that perform the identical steps on the same/identical samples.

Applicants traverses the 35 USC 103 rejections over Zahniser in view of Zweig by analyzing each reference individually. In response to applicant's arguments against

the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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